

ResiQuant® E. coli HCP ELISA Kit-Plasmid

Quantitative sandwich ELISA for residual E. coli host cell protein monitoring in plasmid processes

SENSITIVE LOD 0.5 ng/mL	HIGH COVERAGE 84% antibody coverage*	PLASMID FOCUSED Alkaline lysis process
----------------------------	---	---

Product overview

ResiQuant® E. coli HCP ELISA Kit-Plasmid is a quantitative sandwich ELISA for detection of residual host cell protein (HCP) impurities in plasmid intermediates, crude extracts, and final products produced with Escherichia coli. The assay uses antibodies against denatured E. coli HCP prepared from the alkaline-lysis process and supports process development, manufacturing-process monitoring, and product-release applications.

Key features

- LOD 0.5 ng/mL and LLOQ 1.0 ng/mL; qualified spike recovery range 70%-130%.
- Reported 84% antibody coverage, characterized by antibody affinity extraction and mass spectrometry, including high-risk impurities.*
- Designed for residual E. coli HCP monitoring in alkaline-lysis plasmid intermediates, crude extracts, and final products.
- Quantitative determination using supplied standards and a recommended four-parameter logistic (4PL) standard curve.

INTENDED USE For research and manufacturing use only. Not intended for diagnostic or therapeutic use. This general datasheet does not replace the product label, user manual, Certificate of Analysis, or Safety Data Sheet.

General product characteristics

Parameter	General characteristic
Assay format	Sandwich ELISA
Target analyte	Residual E. coli host cell proteins (HCP)
Host cell	Escherichia coli (E. coli)
Readout	Absorbance at 450 nm; 630 nm or 570 nm reference wavelength optional
Standard curve	Supplied standard; 4PL curve fit recommended
Applications	Plasmid intermediates, crude extracts, and final products

Performance specifications

Parameter	General specification	Parameter	General specification
LOD	0.5 ng/mL	Storage	2-8°C
LLOQ	1.0 ng/mL	Shipping condition	Dry ice
Recovery	70%-130%	Shelf life	12 months
Intra-assay precision	CV ≤15%	Inter-assay precision	CV ≤20%
Accuracy	RSD ≤20%	Kit capacity	48 or 96 reactions

**Coverage and performance values are general product characteristics; confirm current lot-specific documentation before use.*

Assay principle

Microplate wells are coated with antibodies specific for E. coli HCP. Standards or samples and biotinylated anti-E. coli HCP antibody are added to form immunocomplexes with the immobilized antibody. Following washing, streptavidin-HRP is added. After a final wash, TMB substrate produces a color signal that is stopped and measured at 450 nm. Optical density is proportional to E. coli HCP concentration, determined against the supplied standard curve.

Kit contents

Component	96-test kit	48-test kit
E. coli HCP standard	3	2
E. coli HCP microplate	8 × 12 wells	8 × 6 wells
100× biotin-antibody	60 µL	30 µL
100× streptavidin-HRP	120 µL	60 µL
E. coli HCP assay diluent	2 × 25 mL	25 mL
20× wash buffer concentrate	30 mL	30 mL
Substrate solution	12 mL	6 mL
Stop solution	12 mL	12 mL
Plate sealer	3	2
STORAGE Store components at 2-8°C. Protect substrate solution from light. Do not mix or substitute reagents from different lots or kits.		

General assay workflow

Use this as general guidance. Follow the current product user manual for complete instructions, lot-specific requirements, and acceptance criteria.

Step	General procedure
1. Prepare	Equilibrate reagents and samples to room temperature. Reconstitute and prepare the standard curve; prepare 1× wash buffer, biotin-antibody working solution, and streptavidin-HRP working solution.
2. Capture	Add 50 µL standards or appropriately diluted samples and 50 µL biotin-antibody working solution. Incubate at 25°C with shaking (500 rpm) for 60 minutes.
3. Wash	Wash wells five times with 300 µL wash buffer per well.
4. Conjugate	Add 100 µL streptavidin-HRP working solution. Incubate at 25°C with shaking for 60 minutes; wash five times.
5. Develop	Add 100 µL substrate solution; incubate at 25°C in the dark for 15 minutes.
6. Read	Add 100 µL stop solution. Read within 10 minutes at 450 nm, with optional 630 nm or 570 nm reference wavelength.
7. Calculate	Generate a 4PL standard curve, calculate sample concentration, and include applicable dilution factors.

Sample handling and result analysis

- Clarify samples and remove precipitates by centrifugation before testing.
- Perform a suitability study to assess sample-matrix effects and establish suitable dilution conditions.
- Test standards and samples in at least duplicate wells. A standard-curve R² of at least 0.99 is recommended.
- If a sample response exceeds the upper standard, dilute and repeat the measurement; report the dilution-adjusted result.

COMPATIBILITY No cross-reactivity was observed with CHO, Vero, or HEK293 whole-cell lysates under reported test conditions. Confirm suitability for the intended sample matrix.

Materials required but not provided

Microplate reader capable of absorbance measurement at 450 nm (optional 630 nm or 570 nm reference wavelength), adjustable micropipettes and disposable tips, microplate shaker, and deionized or distilled water.

Ordering information

Catalog no.	Product name	Size
CRH00-3041S	ResiQuant® E. coli HCP ELISA Kit-Plasmid	48T
CRH00-3041	ResiQuant® E. coli HCP ELISA Kit-Plasmid	48T
CRH00-3042	ResiQuant® E. coli HCP ELISA Kit-Plasmid	96T

Quality and use notes

- Briefly centrifuge concentrated biotin-antibody and streptavidin-HRP tubes before opening.
 - If crystal sediment appears in the 20× wash buffer concentrate, warm at 37°C until completely dissolved before dilution.
 - Ensure thorough mixing during solution preparation. Test samples and standards in duplicate.
 - Use only reagents from the same kit lot and follow laboratory safety procedures.
- LIMITATION** This datasheet presents general product information. The user is responsible for confirming assay suitability, matrix effects, dilution linearity, recovery, and reportable range for the intended application.

Related documentation

Document	Purpose
User manual	Detailed protocol, reagent preparation, and result interpretation
Certificate of Analysis	Lot-specific release information
Safety Data Sheet	Handling and safety information

Leading Life Technologies

Scientific solutions for bioprocess development and manufacturing

Document: ResiQuant® E. coli HCP ELISA Kit-Plasmid General Datasheet | Rev. 1.0 | 20 August 2026